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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,971	06/09/2005	Yoshihiro Ohmiya	2008_0957	8735
513 7590 05/08/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER NOAKES, SUZANNE MARIE				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/537,971

**Applicant(s)**

OHMIYA ET AL.

**Examiner**

SUZANNE M. NOAKES

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 17 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 March 2009 has been entered.

### ***Status of the Application***

2. The amendments and remarks filed 27 February 2009 are acknowledged. Applicants have amended claim 16. Claims 16, 17 and 22-25 are pending and subject to Examination on the merits.

### ***Withdrawal of Rejections/Objections***

3. Any rejection/objection recited in the previous Office action and not explicitly restated below is hereby withdrawn.

4. The rejection of claim 25, SEQ ID NO: 2, for lacking antecedent basis under 35 USC 112 2<sup>nd</sup> paragraph is withdrawn in view of the amendment to claim 16 to now recite the organism from which the luciferase is derived from is *Vargula hilgendorfi*.

5. The rejection of claims 16, 17 and 22-25 under 35 USC 112 1<sup>st</sup> paragraph, written description and enablement are withdrawn in view of the amendments to the claims.

***New Objections/Rejections – Necessitated by Amendments***

***Specification***

6. The amendment filed 27 February 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: every occurrence of *Cypridina noctiluca* has been changed to *Vargula hilgendorfi*. However, this is deemed as the addition of new matter to the specification because clearly all priority documents recite that the luciferase which embodies the entire description and preferred embodiments are derived from *Cypridina noctiluca* and not once is it mentioned or ever recited that the luciferase is isolated from this *V. hilgendorfi* organism. Many other luciferase's are recited that could encompass the broad and generic aspect of the luciferase-fluorescent fusion protein, for example, Table 2 (p. 11) states the luciferase can be isolated from: *Cypridina noctiluca*, Firefly luciferase (which is from the genus *Photinus*), *Pyrocystis lunula* luciferase; *Renilla* luciferase, however, as noted, no mention of the organism *V. hilgendorfi*.

7. In fact the specification states:

The protein of the present invention can be obtained by incorporating the gene of the present invention described later into the expression vector and expressing it

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in appropriate host cells. As the expression vector, for example, pBT-**VLuc**-mp-YFP (**VLuc**, mp and YFP indicate **Cypridina noctiluca luciferase**, a monitor peptide and the yellow fluorescent protein, respectively) and the like can be used. (see p. 13, lines 27-33).

Furthermore, there is nothing to suggest that this was a simple typographical error (as Applicants assert). It is entirely unclear Applicants intentions at the time of filing; e.g. did Applicants have the right sequence but the wrong organism? Did Applicants have the right organism but the wrong sequence? One skilled in the art can ascertain which was which is the correct scenario and thus this "typographical error" can not be asserted to be an obvious one (also, see written description rejection below for further explanation).

Applicant is required to cancel the new matter in the reply to this Office Action and are also referred to MPEP 2163.06 and 2163.07.

***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph – New Matter***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 16, 17 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 has been amended to delete the organism *Cypridinia noctiluca* and instead replace it with *Vargula hilgendorfi*. The specification likewise has also been amended (as noted above) to replace all occurrences of *Cypridinia noctiluca* with *Vargula hilgendorfi*. However, this introduction of this new organism (which was never previously once recited in the specification or the claims) is deemed as the introduction of new matter.

MPEP 2163 I.B. states:

The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP § 2163.06 through § 2163.07 for a more detailed discussion of the written description requirement and its relationship to new matter. The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An

amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

However, it is noted that the instant amendment is by no means an "obvious error", or an obvious 'typographical error' as Applicants suggest (see Declaration and Remarks, filed 02/27/2009). It is noted that there are several scenarios to the instant alleged error in the application, however, which one Applicants intended cannot be discerned by either the Examiner or one skilled in the art and thus it can not be an "obvious error". Clearly, SEQ ID NO: 2 is the preferred embodiment of the claims and the specification (see for example instant claim 25 and also the specification, p. 6, line 10), Applicants describe in the specification and the previous claims that the luciferase if from *Cypridina noctiluca*. However, it is unclear, and thus unobvious, if: a) Applicants meant to claim the broad independent claim without actually ever having isolated the gene/protein; b) Applicants had the right sequence but named the wrong organism from which the luciferase was derived (which is what Applicants are purporting now); or c) Applicants had the right organism but the wrong sequence. Thus, this can not be interpreted as an "obvious error" for which correction is simplified according to *In re Oda* because one skilled in the art has no idea of the real scenario at the time of filing. Furthermore to assert that *Cypridina noctiluca* is an obvious typographical error as compared to *Vargula hilgendorfi* seems difficult to understand because in the first instance the two organisms are not even close in spelling and second, and second, it is

further pointed out that throughout the Japanese foreign priority document the term *Cypridina noctiluca* was also used and claimed and thus said "typographical error" can not be ascribed to a translation error (see for example, p.1, paragraph 4 of the Japanese foreign priority document).

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to



be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 16, 22 and 23 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-12 and 18 of copending Application No. 10/526,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of the '569 application is drawn to an isolated polynucleotide comprising SEQ ID NO: 1 which encodes a chimeric monitor protein of the following form: a *Vargula* luciferase and yellow fluorescent protein (YFP) which according to Figure 1b, also encodes for a linker peptide between the luciferase and YFP. The other claims are drawn to vectors, transformants and methods of making said chimeric fusion proteins. As such, said encoded protein is an obvious variation of the instant broad and independent claims which is drawn to a method of using such a chimeric fusion protein by quantitatively monitoring the energy change in energy transfer between the YFP and luciferase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. \*\* N.B. It is noted, however, that the above Application has been indicated as allowed and the Issue fee paid.

***Response to Amendment***

12. The Declaration under 37 CFR 1.132 by Ashitaka Emiko, filed 27 February 2009 is insufficient to overcome the rejection of claims 16, 17 and 22-25 based upon the introduction of new matter as set forth in the objection and rejections above. Said Declaration was filed in anticipation of such a rejection and has been considered. However, for the reasons noted in the rejection above, the assertion that the term *Cypridina noctiluca* was an obvious typographical error of the term *Vargula hilgendorfi* is not convincing.

***Response to Arguments***

13. Applicants arguments filed 27 February 2009 have been fully considered. The remarks and amendments to the claims on the one hand are convincing to necessitate the withdrawal of all previous rejections for the reasons set forth above. However, the arguments in anticipation of the introduction of new matter are not convincing for the reasons set forth in the New Matter rejection and objection set forth above

***Reference of Interest – Not Relied Upon***

14. Day et al. "Dual-Function Reporter Protein for Analysis of Gene Expression in Living Cells", *Biolmaging Techniques*, Vol. 25, No. 5, 1998.

***Conclusion***

15. No claim is allowed.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/  
Primary Examiner, Art Unit 1656  
06 May 2009